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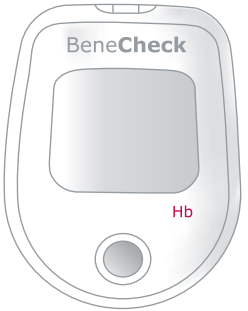
REF PP-E034

07-RN01-UM-01F Jun, 2011

BeneCheck™

Hb Hemoglobin Test System

User's Manual



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Chapter 1 BeneCheck Hb Hemoglobin Test System

1.1 Introduction

Thank you for choosing BeneCheck Hb Hemoglobin Test System. The BeneCheck Hb Hemoglobin Test System is designed by General Life Biotechnology Co., Ltd and marketed all over the world.

The BeneCheck Hb Hemoglobin Test System provides you with accurate hemoglobin results based on electrochemical sensor technology and superior capillary sampling. The BeneCheck Hb Test System requires only a small amount of blood, the hemoglobin level is precisely calculated and displayed less than 10 seconds.

Intended Use :

The BeneCheck Hb Hemoglobin Test System is designed to measure the hemoglobin levels in whole blood. The test strips are for testing outside the body (in vitro diagnostic use). It should be used only for testing hemoglobin with fresh capillary whole blood samples. The system is suitable for healthcare professionals either in blood banks, clinical sites or hospitals to test the hemoglobin levels of blood donors or patients.

The BeneCheck Hb Hemoglobin Test System is calibrated by Sysmex KX-21N Analyzer using venous whole blood. The Sysmex KX-21N is calibrated and referenced according to the NCCLS H15-A3 standard.

Please read the entire USER'S MANUAL carefully before using the BeneCheck Hb Hemoglobin Test System to test your patient's blood hemoglobin levels. This USER'S MANUAL guides you through the operation procedures with illustrated directions and will help you find the required information.

WARNING :
Please carefully read the instructions in the USER'S MANUAL and become familiar with the test procedures before using the system to test blood hemoglobin levels.

1.2 Contents

Please check the package contents for the specific BeneCheck Hb Hemoglobin Test System package. The package may only include partial of the following items :

BeneCheck Hb Hemoglobin Meter
BeneCheck Hb Hemoglobin Test Strip (vial)
Code Strip
BeneCheck Hb Hemoglobin Control Solution
BeneCheck Hb Hemoglobin User's Manual
BeneCheck Hb Hemoglobin Test Strip Instruction
BeneCheck Hb Hemoglobin Control Solution Instruction
Kit Carrying Bag
Lancing Device
Lancets (pack) (Manufacturer : refer to the label on the package)

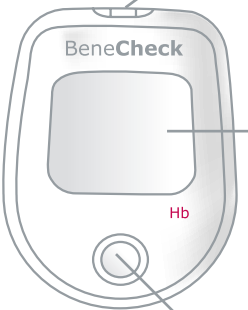
Optional : (not included in the standard kit package, please contact your local distrubutor for ordering.)

BeneCheck Hb Hemoglobin Test Strip(25x1)	BK-H-S001-01E
BeneCheck Hb Hemoglobin Test Strip(25x2)	BK-H-S001-02E

1.3 Labelling and Informations

	Do not re-use		Use by
	Keep dry		Read instructions
	Keep away from sunlight		Caution, consult accompanying documents
	Operation temperature limitation	EC REP	EU Representative
	Storage temperature limitation	REF	Catalogue number (Product number)
	CE certification	IVD	In-vitro diagnostic
	Manufacturer	LOT	Lot number

1.4 System Components
Meter (Front Side)



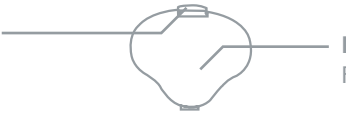
Test Port :
Where you insert the strip for testing.

LCD Screen :
for display of operating information and test results.

Front Button :
for on/off and memory mode operation.

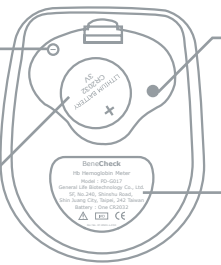
Meter (Back Side)

Battery Cover Lid :
Lift upward when replacing the battery.



Battery Cover :
For covering the battery.

Screw :
For holding the meter together, do not open or dissassemble the BeneCheck Hb Hemoglobin Meter.



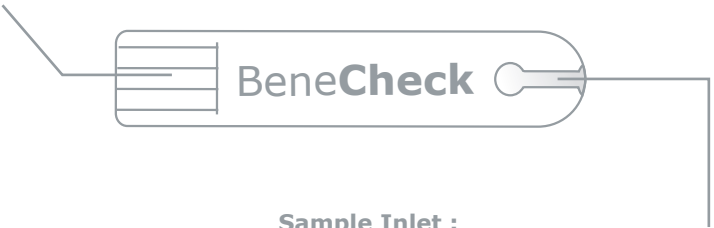
Reset Button :
For setup and reset of the meter.

Battery :
3V lithium battery(CR2032)

Tag :
Display information about the meter.

Test Strip

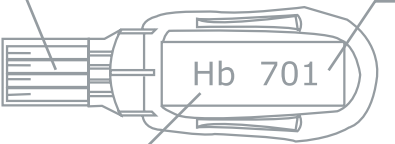
Electronic Contact Bars :
Insert this end of the test strip into the Test Port of the meter to activate it.



Sample Inlet :
The inlet where the whole blood or control solution is drawn in. When a blood sample or control solution touches this end, the sample will be sucked into the reaction zone automatically.

Code Strip (Front View)

Contact Bar :
Insert this end into the Test Port of the meter.



Code Number

Test Mode

Test Mode :
Hb - Hemoglobin

Chapter 2 Setting-up the Meter

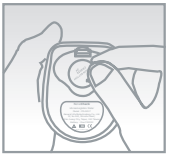
2.1 Installing/Replacing the Batteries

A 3-volt lithium battery (CR2032) is included in the meter package. Use only 3V lithium batteries. Do not use or replace the battery with different types of batteries. Doing so will damage the electronics of the meter.

Instructions :

1.

Hold the meter with one hand, slightly lift the back cover lid to open the back cover.

2. 

Insert a new battery in the meter with the "+" side facing up, you will hear a "beep" sound which indicates that meter is on.

3. Place the cover back onto the meter.

2.2 Set the Year/Month/Day/Hour/Minute/Temperature unit

After a battery is installed in the meter for the first time (as described in 2.1), the meter goes into setting mode automatically.

The directions to setting mode.

Open the battery cover (on the back of the meter), press the setting button then a number such “09” will blink on screen, which means Year.

Set the Year

1. Press the front button to advance one year until you get a correct year number.
2. After you set the desired year number, press the back setting button again then the meter enters into month setting.

Set the Month

1. Press and release the front button until the correct month appears.
2. Press the setting button and the day segment will start blinking.

Set the Day

1. Press and release the front button until the correct day appears.
2. Press the setting button and hour segment will starts blinking.

Set the Hour

1. Press and release the front button until the correct hour appears.
2. Press the setting button and minute segment will start blinking.

Set the Minute

1. Press and release the front button until the correct minute appears.
2. Press the setting button repeatly until the temperature unit (°C or°F) starts blinking.

Set the Unit of Temperature

1. Press and release the front button to select the unit of temperature, °C or °F.
2. Press the setting button when the desired unit is selected. The meter thus completes the setting and turns off automatically.

Set the Measuring mode

1. Press and release the front button to select the measuring mode appear.
2. Press "Front Button" repeatedly until the Hb (hemoglobin) or Hct (hematocrit) mode blinks on top right of the screen.
3. Press the setting button twice to finish the setup.

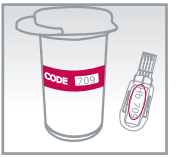
Note :
Please refer to Chapter 5 for the setting procedures of the hemoglobin measurement units.

2.3 Coding the Meter

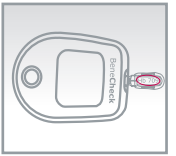
The BeneCheck Hb Hemoglobin Meter should be coded before testing with BeneCheck Hb Test Strips for the first time, or every time a new box of BeneCheck Hb Test Strips is used. Each vial of test strips has an assigned code number. The code strip is packaged with the test strip in order to calibrate/code the meter.

Every time a test strip is inserted, please be sure to check the code number appearing on the screen is the same as the code number marked on the test strip vial.

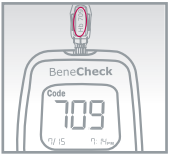
Directions :

1. 

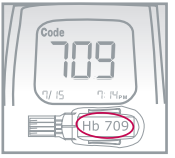
Check the code number on the code strip is the same as the code number on the test strip vial.

2. 

Insert code strip into the test port of the meter.

3. 

Wait for the code number to appear on the screen.

4. 

Make sure the code number on the screen is the same as the code number on the code strip.
Remove the code strip. "☺" should appear on the screen, indicating that the meter has been coded.

Cautions :
If "E-C" appears on the screen after removing the code strip, there may be a problem with the code strip. Perform the coding again, and if "E-C" continues to appear, please contact the original dealer or supplier for service.

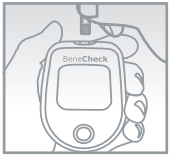
2.4 Control Test

A control solution is used to check the performance of the BeneCheck Hb Test System, including BeneCheck Hb Hemoglobin Meter, BeneCheck Hb Hemoglobin Test Strip, and the user's operating skill. The system performs adequately if the control test result falls within the indicated control range listed on the test strip vial.

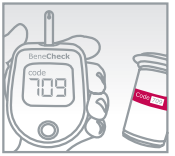
The system should be checked

- When you get the meter for the first time or begin using a new vial of test strip.
- When you suspect that the meter or the test strips are not working properly.
- Any time the hemoglobin test results are not consistent with how you feel, or any time you think your results are not accurate.
- Any time you drop or bump the meter.

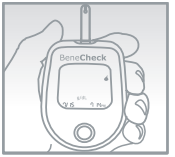
Directions :

1. 

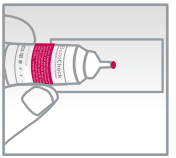
Insert a test strip and immediately cover the vial to keep the other test strips in dry condition. The meter will turn on automatically.

2. 

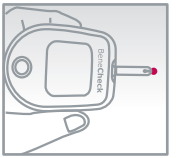
After " CH " and " " appear on the screen, the ambient temperature and code number will follow. Be careful to make sure the code number is the same as the code number marked on test strip vial.

3. 

A blood drop symbol " " blinking on the screen means the system is ready for sample loading.

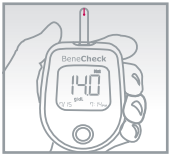
4. 

Please shake well and discard the first three drops of control solution, then drop some control solution onto a clean surface.

5. 

Touch the sample inlet of the test strip to the drop of control solution until the meter sounds a “beep”. The screen will display a countdown.

6.



The screen will display the control test results in Hb(g/dL or mmol/L) and Hct(%) alternately.
Compare the results to the control range listed on the test strip vial.

Hint : Hct is calculated by multiplying 3.00 to Hb

Note :

- Do not reuse test strips.
- Newly opened vials of control solution and test strips must be marked with an opening date.
- Close the test strip vial lid tightly after use.
- Do not use BeneCheck Hb Test System to do any test until you can get the control test result to fall within the range listed on the test strip vial.
- If the test results fall outside the control range, please refer to Chapter 8 for trouble shooting.

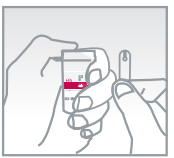
Chapter 3 How to perform a Hemoglobin Test

3.1 Before Testing

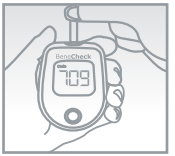
Please follow the step-by-step instructions to ensure accurate test results.
Materials required to perform a hemoglobin test include :

- BeneCheck Hb Hemoglobin Meter
- BeneCheck Hb Hemoglobin Test Strip
- Lancing Device / Lancet
- Tissue or cotton ball with 75% ethanol for wiping blood sampling area after test, or simply wash hands with soap and water throughly before and after test for disinfection.

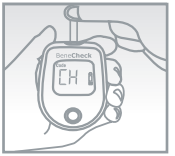
Directions :

1. 

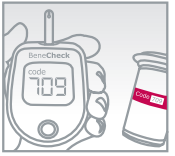
Take a test strip and immediately cover the vial to keep the other test strips in dry condition.

2. 

Fully insert the contact bar of the test strip into the test port of the meter. The meter will turn on automatically.

3. 

After " CH " and " " appear on the screen, the code number will follow.

4. 

Check that code number on the screen is the same as the one on the test strip vial. If not, remove the test strip and recode the meter.

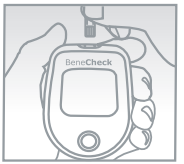
Note :

- The hemoglobin test must be performed within 3 minutes, otherwise the meter will be turned off automatically. If turned off, remove and re-insert the test strip to do the test again.
- Test strips cannot be reused. If an used test strip is inserted, a warning message " E-U " will appear on the screen. Always use new test strips.
- If the wrong end of the test strip is inserted, or if the test strip is inserted backwards the meter will not activate.

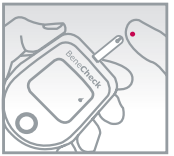
Warning :

- Lancet cannot be reused.
- Please always use certified lancets to ensure safety.

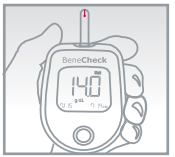
3.2 Perform the Hemoglobin Test Directions :

1. 

Insert the BeneCheck Hb Hemoglobin Test Strip and take a blood sample according to the instructions for lancing device in the system.

2. 

Touch the sample inlet of the test strip to the drop of blood sample until the meter sounds a “beep” that means the sample is drawn into the strip successfully.

3. 

The screen will display a countdown then display the test results in Hb(g/dL or mmol/dL) and Hct(%) alternately after the countdown.

Hint : Hct is calculated by multiplying 3.00 to Hb

Note :

- Please complete the test procedures within 3 minutes or the meter will automatically turn off.
- Do not apply the blood sample on the test strip anywhere other than the sample inlet.
- Do not apply the blood sample to a same test strip twice, it will cause inaccurate test results.

3.3 Care after the Test

Directions :

1. Follow the instructions for lancing device to treat and discard the used disposable lancet into appropriate sharps or biohazard container.
2. After performing a test, remove the test strip and meter will automatically turned off.

Note :

- Please check your system performance regularly or when you suspect your test results are inaccurate.
- Dropping, bumping or other violent impact may damage the meter or cause malfunction.
- Do not use the meter in an environment with possible magnetic, electromagnetic, and radioactive interferences.

Warning :

- Do not disassemble the meter for any reason.
- Please follow local regulations to discard used test strips and lancets.
- Used test strips, lancets and any other materials which have been in contact with blood should be treated as potential biohazards. If an user has an infectious disease, the used test strips and other material could be sources of infection.

Chapter 4 Meter Memory Function

The BeneCheck Hb Meter automatically stores up to 180 records, both hemoglobin test and control test results, each time a test is performed. The memory counts up from M01 through M180. Please follow these directions to recall stored test results.

Directions :

1. Make sure that no test strip is inserted in the meter.
2. Press the "Front Button" once to turn the meter on. A full display will appear on screen after a short "beep" sound.
3. Press the "Front Button" once again before the code number appears. The first stored result will appear on the screen.
4. By pressing the "Front Button" repeatedly, memory number will increase progressively until the final stored result appears, Then the first result will appear on the screen again.
5. To turn the meter off, press the "Front Button" for over 3 seconds and the meter will make a long "beep" sound. The meter will also automatically shut down after 3 minutes.

Note :

- Please complete the test procedures within 3 minutes or the meter will automatically turn off.
- Do not apply the blood sample on the test strip anywhere other than the sample inlet.
- Do not apply the blood sample to the same test strip twice, it will cause inaccurate test results.

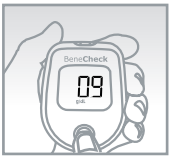
Chapter 5 How to Set the Hemoglobin Measurement Units

Directions :

1. Make sure that no test strip is inserted in the meter.
2. Open the battery cover of the meter, press "Setting Button" once then a blinking number "01" will appear on Screen and start year, date... setting. (See Fig.1-3)

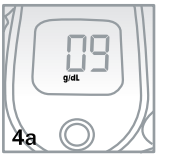
1

2

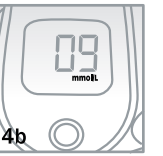
3 

3. Others setting, please see Chapter 2 Setting-Up the Meter.

4. After setting temperature, press "setting button" for "Measuring mode" setting. Pressing the "Front Button" repeatedly until the Hb (hemoglobin) or Hct(hematocirt) mode blinks on for right of



4a



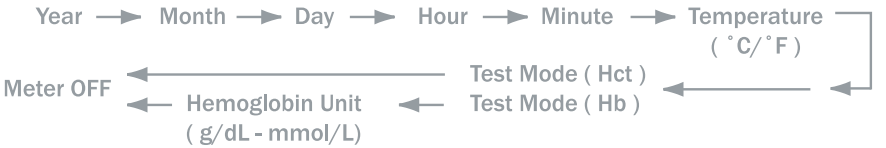
4b

the screen. Pressing the "Front Button" will switch between "g/dL" and "mmol/L" when "Hb" mode is selected. When set at "Hct" mode, only "%" will be displayed. (See Fig.4a&4b)

5. Press the "Setting Button" when desired unit is selected then the meter completes the setting and turns off automatically.

Note :

- The Setting items of the meter is listed as follows. Please be careful to set the desired hemoglobin unit.



Chapter 6 Storage and Handling of Meter and Strips

Due to sensitive to heat and humidity, the performance of test strips may be affected by improper storage and handling. Please store the test strips and meter carefully according to the specifications listed in Chapter 9.

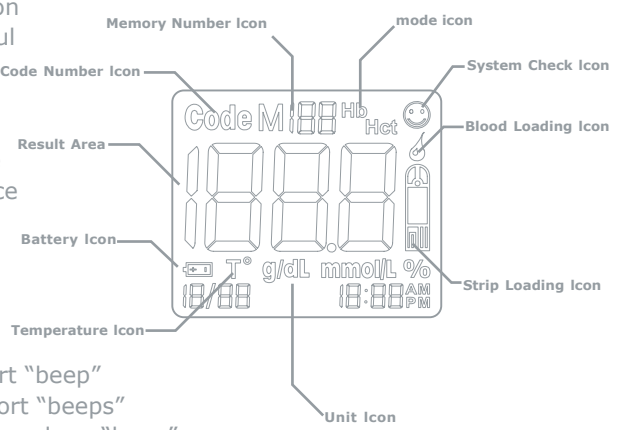
Note:

1. Store the meter, code strip, test strips and control solution at room temperature. Do not expose them beyond the range described in Chapter 9.
2. Do not freeze or refrigerate the meter and strips.
3. Keep the meter clean by wiping the exterior of the meter with a tissue or lint-free cloth.

Chapter 7 Icon and Alert Tones

7.1 Icon on the Screen

The vivid and clear information icons on the screen are helpful and convenient. In addition to providing accurate blood hemoglobin test results, the icon design on the screen are easy to understand at a glance and will save you the effort of carrying the User's Manual for reference.



7.2 Alert Tones

- Normal Alert Sound : a short "beep"
- Warning Alert Sound : 5 short "beeps"
- Turning On/Off Alert Sound : a long "beep"

Chapter 8 Error Message and Trouble Shooting

Message	Cause	Solution
E-0	There may be a problem with the meter or code strip.	Repeat the test with a new code strip. If the problem persists, please contact the dealer for service.
E-9	The test strip may be removed after applying blood the absorbent hole.	Review the instructions and try again with a new test strip. If the problem persists, please contact the dealer for service.
E-A	There is a problem with the meter.	Review the instructions and try again with a new test strip. If the problem persists,please contact the dealer for service.
E-b	The power of the battery is too low to run a test.	Replace the battery at once.

Message	Cause	Solution
E-C	Usage of the code strip was inserted improperly, damaged, or incorrect.	Check that the code number on the meter display matches the code number on the test strip vial. Code the meter or retest as necessary. If the error message appears again, please contact the dealer for service.
E-t& **Tm Sign**	The temperature was below or above the system operating range.	Repeat the test after the meter and the test strip have reached the temperature within the operating range.
EU	It could be caused by an used test strip or a temporary or permanent electronic problem.	Repeat the test with a new test strip. If the error message appeare again, please contact the dealer for service.

Message	Cause	Solution
Hi	1. Hemoglobin(Hb) level is higher than 26.0 g/dL (or 16.1 mmol/L), or hematocrit (Hct) level is higher than 75%. 2. Test strip has a problem.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.
Lo	1. Hemoglobin(Hb) level is lower than 7.0 g/dL (or 4.3 mmol/L), or hematocrit (Hct) level is lower than 20%. 2. Test strip has a problem.	1. Review the instructions and try again with a new test strip. 2. Check the test strip vial to make sure that it is not marked beyond the expiration date.

Chapter 9 Specifications

System Accuracy	:	± 20% at hemoglobin level > 7.0 g/dL
Test Sample	:	Capillary whole blood
Measuring Time	:	Less than 10 seconds
Measuring Range	:	7.0 - 26.0 g/dL (4.3 - 16.1 mmol/L) ; 20 - 75% Hct (calculated)
Sample Volume	:	About 1 µL
Strip Storage Condition	:	10 - 30°C
Operation Temperature	:	10 - 40°C
Relative Humidity	:	Less than 95%
Memory	:	180 test results
Battery Type	:	One 3V (CR2032) lithium battery
Battery Life	:	Approximately 1,000 tests
Dimensions	:	61*77*19 mm
Weight	:	About 47g (battery not included)

Chapter 10 Limitations

Please observe the following limitations for obtaining accurate results of BeneCheck Hb Hemoglobin Test System :

1. For In-vitro diagnostic use only (External use only).

2. Do not dispose test strips in high humidity or in direct sunlight. Do not freeze the strips.

3. BeneCheck Hb Hemoglobin Test Strip is for single use only, please do not reuse the test strip.

4. Handle the strip with clean and dry hands; lancing site for the test should be cleaned and dried thoroughly.

5. Do not perform a test while a using a cell phone; doing so will cause the electronic signal interference.

6. Oxygen concentration in air may cause inaccurate test results.

7. User Variability : hemoglobin test is technique sensitive. Only well trained professionals can operate the test system. Lay person is not recommended to use for self-test.

8. Only capillary finger blood can be used for tests, other specimen such as venous blood may cause inaccurate tests result.

9. The following substances may interfere with test results when at higher level concentration : ascorbic acid, bilirubin, sodium and uric acid.